



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/626,076

07/24/2003

Andrea Venturelli

71067

4532

24633 7590 09/24/2009
HOGAN & HARTSON LLP
IP GROUP, COLUMBIA SQUARE
555 THIRTEENTH STREET, N.W.
WASHINGTON, DC 20004

EXAMINER

MEHTA, BHISMA

ART UNIT

PAPER NUMBER

3767

NOTIFICATION DATE

DELIVERY MODE

09/24/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

dcptopatent@hhlaw.com
rogruwell@hhlaw.com

Office Action Summary	Application No. 10/626,076	Applicant(s) VENTURELLI, ANDREA	
	Examiner BHISMA MEHTA	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 5, 2009 has been entered.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose the portion of the guide tube near the proximal end of the guide tube covering the entire outside of the deflected and inclined portion of the main tube. The specification also fails to disclose the proximal end of the guide tube extending past the deflected and inclined portion of the main tube.

Claim Objections

3. Claims 24-27 are objected to because of the following informalities: The status identifier of claim 24 is incorrect as it is not a new claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wijeratne et al (U.S. Patent No. 6,036,670) in view of Miraki (U.S. Patent 5,389,087). In Figure 2, Wijeratne et al show or provide a distal tube (22) with a flared proximal end (at 38), a guide tube (23) with a proximal end (26), and a main tube (32) with a distal end (37). As seen in Figure 2, a portion of the main tube near the distal end (37) of the main tube is deflected and inclined towards the axis of the main tube. The deflected and inclined portion (or at least part of the deflected and inclined portion) of the main tube (32) is inserted into the distal tube flared proximal end (100) so that a portion (at 26) of the guide tube (23) near the proximal end of the guide tube covers a section of the outside of the deflected and inclined portion. Wijeratne et al teach joining or fixing the distal end (37) of the main tube, the proximal end (26) of the guide tube, and the flared proximal end (at 38) of the distal tube to one another by means of a heat-sealing operation (line 42 of column 5 to line 14 of column 6). As seen in Figure 2, the guide tube (23) is inserted into the distal tube (22) such that the guide tube proximal end (26) exits and extends from the distal tube flared proximal end (at 38). Wijeratne et al disclose the method for manufacturing the catheter structure substantially as claimed. However, Wijeratne et al are silent on the insertion of a first expander into the distal end

Art Unit: 3767

of the main tube and a second expander into the proximal end of the guide tube and on the extraction of the first and second expanders once the sealing has been performed. Miraki teaches inserting expanders into the ends of tubes that will become a lumen for a guidewire or an inflation lumen and removing the expanders after use in the same field of endeavor of using heat-sealing to join the different sections of a catheter structure (lines 51-68 of column 7 and line 40 of column 12 to line 52 of column 13). The expanders maintain the shape of the tubes in the area or zone where the tubes are to be sealed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the lumens of Wijeratne et al by using expanders as taught by Miraki as both Wijeratne et al and Miraki disclose securing the ends of the tubes at a seal area (lines 1-36 of column 13 of Wijeratne et al and line 42 of column 5 to line 14 of column 6 of Miraki) and Miraki teaches that it is well known to use expanders to form lumens when using heat-sealing to form a catheter structure. Even though Wijeratne et al disclose at least a part of the deflected and inclined portion of the main tube (32) being inserted into the distal tube flared proximal end (100) so that a portion (at 26) of the guide tube (23) near the proximal end of the guide tube covers a section of the outside of the deflected and inclined portion, Wijeratne et al are silent on the specifics of a portion of the guide tube near the proximal end of the guide tube covering the entire outside of the deflected and inclined portion so that the proximal end of the guide tube extends past the deflected and inclined portion of the main tube. Miraki shows a guide tube (78) with a proximal end (at 64 in Figure 18) and a main tube (40) with a distal end where a portion of the main tube near the distal end (as shown at

Art Unit: 3767

68 in Figure 18) is deflected and inclined towards the axis of the main tube. In Figure 18, Miraki show that the a portion of the guide tube (78) near the proximal end of the guide tube covers the entire outside of the deflected and inclined portion of the main tube so that the proximal end of the guide tube extends past the deflected and inclined portion of the main tube. It would have been obvious to one having ordinary skill in the art at the time the invention was made to insert the deflected and inclined portion of the main tube of Wijeratne et al into the flared proximal end of the distal tube of Wijeratne et al such that the portion of the guide tube near the proximal end of the guide tube of Wijeratne et al covers the entire outside of the deflected and inclined portion of the main tube as taught by Miraki as Miraki teaches that it is well known that the outside of the deflected and inclined portion is entirely covered so that the proximal end of the guide tube extends past the deflected and inclined portion of the main tube as this enables the physician to more easily insert and guide a guidewire through the guide tube and into the lumen of the main tube (lines 27-52 of column 13)..

6. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wijeratne et al in view of Miraki as applied to claim 24 above, and further in view of Fitzmaurice et al (U.S. Patent No. 5,823,995). Wijeratne et al and Miraki disclose the method for manufacturing the catheter structure substantially as claimed. However, Wijeratne et al and Miraki are silent on the specifics of inserting the guide tube into the distal tube before the step of inserting the two expanders. Fitzmaurice et al disclose a method of manufacturing a catheter structure where different components of the catheter structure are assembled before the insertion of expanders or mandrels.

Art Unit: 3767

Specifically, the wire assembly (14, 50) is placed in the proximal shaft (32) before the mandrel (37) is inserted between the wire assembly and the proximal shaft (lines 36-48 of column 4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to insert the guide tube into the distal tube of Wijeratne et al before inserting the expanders as taught by Fitzmaurice et al as Fitzmaurice et al teach that it is well known to assembly the different components of a catheter structure before inserting expanders into the components.

7. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wijeratne et al in view of Miraki as applied to claim 24 above, and further in view of Ressemann et al (U.S. Patent No. 6,004,291). Wijeratne et al and Miraki disclose the method for manufacturing the catheter structure substantially as claimed. Even though Wijeratne et al show the guide tube (23) with an opening (27) on one side of the main tube, Wijeratne et al and Miraki are silent on the specifics of beveling the guide tube proximal end so that the guide tube has an opening on one side of the main tube and further are silent on the step of beveling the guide tube proximal end being carried out after the step of extracting the expanders. Ressemann et al disclose a method of manufacturing a catheter structure where a component of the structure, tubing (23), is trimmed to a desired length (lines 7-8 of column 7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of manufacturing the catheter structure of Wijeratne et al with a step of beveling as taught by Ressemann et al as Ressemann et al teach that it is well known to trim components of a catheter structure to the desired length where the length would be

Art Unit: 3767

dependent on the use of the catheter structure. To bevel the guide tube proximal end after the extracting of the expanders would have been obvious to one having ordinary skill in the art at the time the invention was made as it would be difficult and impractical to trim the proximal end of the guide tube while an expander is present in the guide tube.

Response to Arguments

8. Applicant's arguments, see line 18 of page 5 to line 4 of page 6, filed August 5 2009, with respect to the objection to the specification have been fully considered and are persuasive. The objection of the specification has been withdrawn.

9. Applicant's arguments, see line 8 of page 6 to line 16 of page 7, filed August 5 2009, with respect to the 112, 1st paragraph rejection have been fully considered and are persuasive. The 112, 1st paragraph rejection of the claims 25-27 has been withdrawn.

10. Applicant's arguments, see line 19 of page 8 to line 6 of page 9, filed August 5 2009, with respect to the rejection(s) of claim(s) 23 under 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Wijeratne et al in view of Miraki as detailed above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-

Art Unit: 3767

3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767